Warner-Lambert Company 170 Tabor Road Morris Plains, NJ 07950 973-540-6713 Fax: 973-631-7760

Sr. Director Medical Affairs Medical and Clinical R&D

Howard M. Druce, M.D., F.A.C.P.

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Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" St., SW Washington, D.C. 20204

Re: Section 403(r)(6) Notification

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act and Food and Drug Administration regulations at 21 CFR 101.93, this letter serves as notification that, less than 30 days ago, Warner-Lambert Company commenced marketing Quanterra Sinus Defense. This product contains a combination of the following herbs: *Gentiana lutea*, *Sambucus nigra, Verbena officinalis, Primula veris* and *Rumex acetosa*. The label of the product bears statements of nutritional support.

The statements of nutritional support are as follows:

Principal Display Panel

- "Maintains Healthy, Clear Sinus Passages"
- "Promotes and Maintains Sinus Health"

Back Panel

- "Maintains healthy, open sinus passages."
- "Quanterra SINUS DEFENSE is the unique and proprietary herbal combination, Sinupret®, that naturally maintains healthy sinus functions, especially drainage and secretion."
- "Sinupret® is a unique and proprietary combination of five herbs, especially designed to work naturally with your body, maintaining clear and healthy sinus passages."

The undersigned certifies his good faith belief that the information contained in this notice is complete and accurate, and that Warner-Lambert Company has substantiation that the statements are truthful and not misleading.

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Thank you for your attention to this matter.

Sincerely,

Dr. Howard Druce

Senior Director, Medical Affairs

Warner-Lambert Consumer Healthcare